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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/795,873

03/08/2004

Jean-Pierre Hermet

1049-04

3189

35811 7590 01/08/2010
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EXAMINER

HINES, JANA A

ART UNIT

PAPER NUMBER

1645

NOTIFICATION DATE

DELIVERY MODE

01/08/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pto.phil@dlapiper.com

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/795,873	Applicant(s) HERMET ET AL.	
	Examiner JaNa Hines	Art Unit 1645	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 01 December 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: _____.
- Claim(s) objected to: _____.
- Claim(s) rejected: _____.
- Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See continuation sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Mark Navarro/
Primary Examiner, Art Unit 1645

The rejection of claims 1-5, 8, 10, 14-17, 23-27 and 37-38 under 35 U.S.C. 103(a) as being unpatentable over Doshi et al., and Aunet et al., in view of Zierdt et al., is maintained because it would have been prima facie obvious at the time of applicants' invention to modify the method of Doshi et al., to include an enclosed and sterile device of Aunet et al., and the lysing step and second filter that retains contaminating microbes and allows passage of cellular debris as taught by Zierdt et al., because Zierdt et al., teach that the lysis reaction increases the amount of bacteria retained by the filter and thereby removed from the blood; while Aunet et al., teach a safe device to allow blood analysis without contamination.

Applicants argue that Doshi do not teach a lysis step; however Zierdt et al., teach that the lysis reaction increases the amount of bacteria retained by the filter and thereby removed from the blood; thus no more than routine skill would have been necessary to include an enclosed device, a lysis reagent and step, since the art teaches that it is desirable to rid a blood sample of substantially all blood cells since it is difficult to conduct an analysis of the blood components without interference from external sources and red blood cells when testing for microbial contamination. Contrary to applicants' assertions that Zierdt selective lysis; Zierdt et al., teach selectively lysing the cells and recovering microbes with second filter having a pore size of about 0.3um to less than 1um which retains contaminating microbes and allows passage of cellular debris; running the lysed blood samples through a filter sized at 0.45um which thereby has a pore size of about 0.3um to less than 1um and can retain contaminating microbes yet allow passage of cellular debris to teach superiority and increased sensitivity of the lysis-filtration procedures for detection of bacteremia.

Applicants assert that Aunet et al., do not teach an enclosed or sterile device. However Aunet et al., teach a housing which not only holds but encloses the device matrices whereby the only means for sample introduction to the porous matrices is by the inlet port. Aunet et al., also teach an exit port for which the sample exits. Thus the matrices are clearly enclosed since the only way for sample to enter and exit is by the inlet and exit port. Aunet et al., teach a device comprising an enclosed and sterile housing, entry and exit ports (col. 5-6, lines 67-3). Furthermore, the matrices are within the housing; therefore if the matrices are within the housing then it is the position of the Office that the matrices are enclosed. Therefore applicants' arguments are not persuasive and the rejection is maintained.

The rejection of claims 6 and 7 under 35 U.S.C. 103(a) as being unpatentable over Doshi et al., and Zierdt et al., further in view of Cathey et al., is maintained because contrary to applicants' assertions, no more than routine skill would have been necessary to include a fluorescence marker in the method of detection, since the art teaches that it is desirable to use fluorescence detection signals to detect analytes and other microbes.

The rejection of claims 9 and 13 under 35 U.S.C. 103(a) as being unpatentable over Doshi et al., Aunet et al., and Zierdt et al., further in view of Besson-Faure et al., is maintained because there would have been a reasonable expectation of success in this modification since only routine skill would have been required to use antibodies as agglutinating agents when the prior art provides motivation for antibody agglutinating agents wherein the motivation is that antibodies are reactive, well known for agglutinating properties and recognize glycoproteins; and Besson-Faure et al., provide commercially available anti-GpIIb/IIIa agglutinating antibodies that cause high affinity agglutination; contrary to applicants' arguments.